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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/986,392	11/08/2001	Graham Smith	00167-441001	5656

7590
JOEL R. PETROW
Smith & Nephew, Inc.
1450 Brooks Road
Memphis, TN 38116

06/04/2003

EXAMINER

PHANIPHAND, GWEN G

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 06/04/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/986,392

Applicant(s)

SMITH, GRAHAM

Examiner

Gwen Phanijphand

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-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

RESPONSE TO AMENDMENT

Claim Rejections – 35 U.S.C. 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,149,669 to Li in view of U.S. Patent No. 6,066,160 to Colvin et al.

Regarding claim 1, Li discloses in col. 1, ll. 22-25 an anchor configured to be retained within bone with an aperture for coupling a flexible member to the anchor (Fig. 2, element 63; Fig. 5, element 63). Li discloses the anchor body but does not disclose a generally stationary restrictor to selectively restrict movement of a flexible member coupled thereto. Colvin et al., however, disclose in Fig. 1 a means (20) of restricting the movement of a flexible member, such that the flexible member moves through the anchor body in a first direction while movement in a second opposite direction is restricted (col. 8, ll. 62-64). Colvin et al. also disclose that the means of restricting a flexible member may be incorporated into anchor bodies used in the bone (col. 4, ll. 10-18). This is advantageous because it eliminates the extra step of tying knots in the ends of the flexible member. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the flexible member aperture of the Li with the restrictor of the aperture of Colvin et al. The restrictor of the aperture of Colvin et al. holds the flexible member and comprises a means of restricting the flexible member, allowing the flexible member to be held without ties or knots at the ends. This means of restriction creates versatility for terminating sutures and securing tissue anchors in place.

Regarding claim 2, Colvin et al. disclose in Fig. 1 a restrictor (ridges, 20) in the aperture of the modified bone anchor configured to engage the flexible member and selectively restrict movement of the flexible member (col. 8, ll. 62-64).

Regarding claim 3, Colvin et al. disclose the restrictor of the modified bone anchor configured to engage the flexible member at a substantially arbitrary position along the length of the flexible member (col. 4, ll. 57-63). It is at the surgeon's discretion to decide where to engage the flexible member, restricting its length in one direction.

Regarding claim 4, Colvin et al. disclose in Fig. 1 an opening or aperture (14A) of the modified bone anchor through which the flexible member can be moved.

Regarding claim 5, Colvin et al. disclose in Fig. 1 a restrictor (20) of the modified bone anchor configured to engage the flexible member and to selectively restrict passage of the flexible member through the opening (col. 8, ll. 62-64).

Regarding claim 6, Colvin et al. disclose in Fig. 1 the restrictor (20) of the modified bone anchor, defining at least a part of the opening. The ridges are formed on the aperture and protrude toward the opening (col. 4, ll. 57-59).

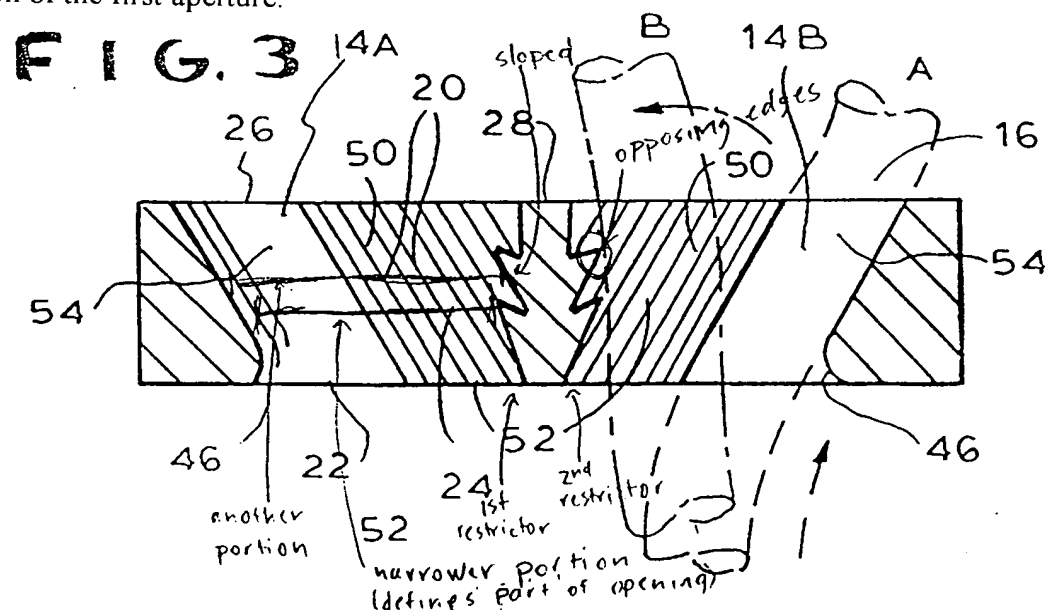
Regarding claim 7, Colvin et al. disclose in Fig. 1 the restrictor (20) of the modified bone anchor, defining a narrower portion of the opening than another portion of the opening. The ridges, which are formed on the aperture, point and extend inward (Fig. 3) creating a narrower portion than in another portion.

Regarding claim 8, Colvin et al. disclose in Fig. 3 the restrictor (20) of the modified bone anchor, including a sloped surface configured to compress the flexible member to permit passage of the flexible member through the opening (col. 8, ll. 58-64).

Regarding claim 9, Colvin et al. disclose in Fig. 3 the restrictor (20) of the modified bone anchor, including opposing edges for engaging the flexible member to restrict passage of the flexible member through the opening (col. 8, ll. 58-64).

Regarding claim 10, Colvin et al. disclose in Fig. 2 a second restrictor (20) of the modified bone anchor, which is located on aperture 14B and configured to engage the flexible member to selectively restrict passage of the flexible member through the opening (col. 8, ll. 58-64).

Regarding claim 11, Colvin et al. disclose the restrictors are oppositely directed. (col. 5, ll. 24-38). Colvin et al. explain that the first direction of the first aperture and the second direction of the second aperture are directed upwards. This means that the first direction of the second aperture is directed downwards, which is the opposite direction of the first direction of the first aperture.



Regarding claim 12, Li discloses in Figs. 1A and 2 the anchor body including a pair of legs (48).

Regarding claim 13, Li discloses in Fig. 10 the anchor body including a bone-engaging ridge (49) for retaining the bone anchor in a bone hole (50).

Regarding claim 14, Li discloses in Fig. 2 the anchor body comprising a unitary body.

Regarding claim 15, Li discloses in Fig. 2 the anchor body including a post (42) about which the flexible member is positionable.

Regarding claims 16, 17, 18, and 19, Li discloses in Fig. 10 a system comprising first and second anchor bodies that include members (49) to retain the anchors in the bone (54). The first and second anchor bodies also define apertures (Fig. 2: element 63; Fig. 5, element 63) for receiving a suture or flexible member (60), which in Fig. 10 couples the first and second anchor bodies. In Fig. 4, one strand of the flexible member or suture (60) can be pulled, and this will shorten the length of the other strand of the flexible member between the bone anchors (see strands a and b in Fig. 4 inserted below). Li does not disclose the anchors comprising a generally stationary restrictor configured to receive a flexible member. Colvin et al., however, disclose in Fig. 1 an aperture with a generally stationary means (20) of restricting the movement of a flexible member coupled thereto, such that the flexible member moves through the anchor body in a first direction while movement in a second opposite direction is restricted (col. 8, ll. 62-64). The restrictor of Colvin et al. does not require that the flexible member have an enlarged portion to restrict its movement. Colvin et al. state that this means of restricting a flexible member can be incorporated into anchor bodies used in the bone (col. 4, ll. 10-18). The means of restricting movement of a flexible member of Colvin et al. is advantageous because it allows the anchors to hold the flexible member without tying knots. It would

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have been obvious to one having ordinary skill in the art at the time of the invention to modify the flexible member aperture of Li with the restrictor of the aperture of Colvin et al.. The aperture holds the flexible member (suture) and the means of restricting the flexible member allows the flexible member to be held without ties or knots. Placement of the means of restricting in both anchor bodies creates one-way passages through which the suture that couples the first and second anchor bodies extends. This means of restriction creates versatility for terminating sutures without knots and hence, eliminates the extra step and bulk of tying a knot.

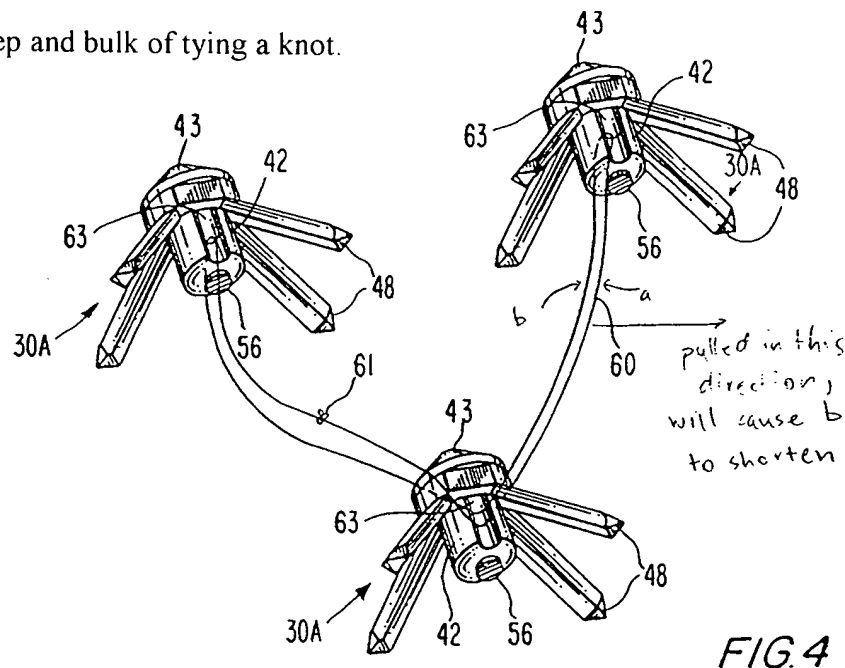


FIG. 4

Regarding claim 21, Colvin et al. disclose in Fig. 3 the restrictor (20) of the modified anchor, including a sloped surface configured to compress the suture to permit passage of the suture through the one-way passage (col. 8, ll. 58-64).

Regarding claim 22, Colvin et al. disclose in Fig. 3 the restrictor (20) of the modified anchor, including opposing edges for engaging the flexible member to restrict passage of the flexible member through the one-way passage (col. 8, ll. 58-64).

Regarding claims 23 and 24, Li disclose in Fig. 5A first and second anchors that are retained in the bone (54). The first and second anchors define apertures for a flexible member. The anchors of Li, however, do not comprise generally stationary restrictors, which allow the movement of a flexible member in the first direction and restrict the movement of the flexible member in a second, opposite direction. Colvin et al. disclose in Fig. 3 a restrictor (20) in an aperture, defining an opening having a first portion for permitting passage of a member therethrough and second portion restricting the passage in a second opposite direction (col. 8, ll. 62-64). Colvin et al. state that this means of restricting a flexible member by the restrictor can be incorporated into anchor bodies used in the bone (col. 4, ll. 10-18). The restrictor is advantageous because it allows the anchor to hold the flexible member without tying knots. It would have been obvious to one having ordinary skill in the art at the time of the invention to improve the anchor bodies of Li by modifying the flexible member aperture of each anchor body with a restrictor of Colvin et al. The aperture holds the flexible member (suture) and further comprises a means of restricting the flexible member, allowing the flexible member to be held without ties or knots. The restrictor eliminates the extra step of tying knots.

Regarding claim 25, Li discloses in Fig. 5A a second anchor in the bone (54). The second anchor is coupled to the first anchor by a flexible member (60). In Fig. 4, if one strand of the flexible member is pulled in a first direction (e.g. away from the other strand), the length of the flexible member between the anchors may be shortened.

Regarding claim 26, the modified aperture of Li to Colvin et al. discloses restrictors such that passage of the flexible member through both restrictors is permitted when one end region of the flexible member is pulled, and passage of the flexible

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member through both restrictors is restricted when an opposite end region of the flexible member is pulled (col. 8, ll. 62-64). If both of the apertures (element 63) in Fig. 5 are modified to contain the means of restriction of Colvin et al., then the flexible member will be restricted when pulled in an opposite direction against the permissible direction.

Regarding claim 27, the modified invention of Li to Colvin et al. discloses the repair system wherein the suture can be moved through the first and second anchor bodies (Li: Fig. 5) to shorten a length of the suture between the first and second anchor bodies, while, without the aid of an enlarged portion on the suture, lengthening of the suture between the first and second anchor bodies is restricted (Colvin et al.: col. 8, ll. 62-64). If the apertures of Li are modified to contain the means of restriction of Colvin et al. then lengthening the suture between the first and second anchor bodies can be restricted by the restrictor of Colvin et al. The means of restriction only allow the suture to travel in one direction.

Regarding claim 28, Colvin et al. disclose in Fig. 3 the restrictor (20) including a sloped surface configured to compress the flexible member to permit passage of the flexible member through the first restrictor (col. 8, ll. 58-64).

Regarding claim 29, Colvin et al. disclose in Fig. 3 the restrictor (20) including opposing edges for engaging the flexible member to restrict passage of the flexible member through the restrictor (col. 8, ll. 58-64).

Regarding claim 30, Li discloses in Figs. 1A and 2 the anchor wherein the anchor body includes legs (48) extending distally from the one way passage and having inner walls that define an opening. A wall (44) extends along a side of the anchor body that is

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distal the legs. Li further discloses a post (42) about which the flexible member is positionable. The post extends from the wall.

Regarding claim 31, Li discloses in Fig. 5A a bone anchor comprising an anchor configured to be retained within bone and an opening for a flexible member (63). Li, however, does not disclose the opening selectively restricting movement of a flexible member coupled thereto. Colvin et al. disclose in Fig. 3 a restrictor insertable into an anchor that defines an opening bounded by a sloped wall (Fig. 3: element 20; col. 4, ll. 10-18). The sloped wall is configured to compress the flexible member to permit passage of the flexible member through the opening in a first direction and further comprises a portion to restrict the passage of the flexible member through the opening in a second, opposite direction (col. 8, ll. 58-64). The means of restriction in the device of Colvin et al. is advantageous because it allows the flexible member to be adjusted and then held without the extra step of tying knots in the ends. It would have been obvious to one having ordinary skill in the art at the time of the invention to include the means of restriction of Colvin et al. in the apertures of Li, so that surgeon does not need to tie the ends of the sutures that travel through the apertures.

Response to Arguments

Applicant's arguments filed 5/5/03 have been fully considered but they are not persuasive. Regarding the combination of Li and Colvin et al., the invention of Li uses knots to tie the ends of the suture that travel through the apertures (col. 4, ll. 2-7). Hence, modifying of the aperture of Li with the means of restriction of Colvin et al. is advantageous, since the physician can eliminate the extra step of tying knots. Adding the

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means of restriction of Colvin et al. would not destroy the invention of Li because the length of suture in the device of Li can still be fixed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gwen Phanijsphand whose telephone number is 703-305-4845. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

GP *GP*

May 30, 2003

Gwen Phanijphand
Patent Examiner
Art Unit 3731


Michael J. Milano
Supervisory Patent Examiner
Technology Center 3700